

Applicant : Peters et al.  
Appl. No. : 10/595,601  
Examiner : Luther G. Behringer  
Docket No. : 13634.4011

In the Claims

Please amend claims 1-5, 8, 24 and 36 and add new claims 37-38 as follows:

1. (Currently Amended): In aA method of controlling the operation of a co- or counter pulsation aortic pulsatile heart assist device comprising a balloon implanted in a patient, the improvement comprisingconsisting of utilizing sounds produced by the heart to control the operation of the heart assist device.
2. (Currently Amended): The method as claimed in claim 1, wherein the method uses a combination of R-wave detection and heart sound detection to control the operation of the heart assist device.
3. (Currently Amended): The method as claimed in claim 1, wherein the heart assist device is completely controlled by utilizing both the S1 and S2 sounds of the heart to both stop and start the heart assist device.
4. (Currently Amended): In aA method of controlling the operation of a pulsatile heart assist device coupled to the aorta ofin a patient, the improvement comprisingconsisting of electrically detecting the R-wave of the patient's heart rhythm and producing a signal to initiate a change in the pulsatile status of the heart assist device, and detecting a sound or pressure wave created by the closure of the patient's aortic valve and producing a signal to return the heart assist device to the pulsatile <sup>f</sup>status it had before the preceding R-wave.

5. (Currently Amended): A method of controlling the operation of an aortic pulsatile heart assist device with a multi-channel digital signal processor and transmitter (DSPT), the

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DSPT being of the type having an ECG channel and a phonocardiographic (PCG) channel, the DSPT being at least adapted to normally sense an electrical signal indicative of cardiac rhythm through the ECG channel, and to normally sense heart sounds through the PCG channel coupled with a microphone, and to transmit signals to an external receiver, ~~the method comprising the steps of~~ operatively connecting ~~at~~ the DSPT bipolar ECG lead to a patient's heart; and operatively connecting the DSPT microphone to the patient's heart, whereby, after detecting an R-wave via the ECG channel, the DSPT issues a R- wave signal to the heart assist device controller to control the timing of the pulsation of the heart assist device, and whereby, after detecting a heart sound via the PCG channel, the DSPT issues a heart sound signal to the heart assist device controller to control the timing of the pulsation of the heart assist device.

6. (Original): The method as claimed in claim 5, wherein the DSPT is adapted to normally sense heart sounds through the PCG channel in the range of 20-500 Hz.

7. (Previously Presented): The method as claimed in claim 5, wherein the DSPT is able to receive as well as transmit.

8. (Currently Amended): The method as claimed in claim 58, wherein the DSPT has parameter settings adjusted within ranges, for detecting the R-wave and the heart sounds, and for the output signals.

9. (Previously Presented): The method as claimed in claim 5, wherein the ECG lead connected to the patient's heart is epicardial or endocardial or attached to an implanted heart assist device itself.

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10. (Previously Presented): The method as claimed in claim 5, wherein sensors for the collection of an ECG signal are embedded into the surface of a heart assist device applied to the heart or another part of the patient's body from which an ECG signal may be received.

11. (Previously Presented): The method as claimed in claim 5, wherein the DSPT microphone is internal to the patient's body.

12. (Original): The method as claimed in claim 11, wherein the connection to the patient's heart is epicardial.

13. (Original): The method as claimed in claim 11, wherein the connection to the patient's heart is endocardial.

14. (Original): The method as claimed in claim 11, wherein the connection to the patient's heart is in the manner of a pacing lead.

15. (Original): The method as claimed in claim 11, wherein the connection to the patient's heart is attached to the implanted device itself.

16. (Original): The method as claimed in claim 11, wherein the connection to the patient's heart is located within 50 mm of the cardiac valves.

17. (Original): The method as claimed in claim 11, wherein the connection to the patient's heart is without the lung between the microphone and the patient's heart.

18. (Previously Presented): The method as claimed in claim 5, wherein the microphone is positioned outside the body of the patient.

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19. (Original): The method as claimed in claim 18, wherein the heart sounds and ECG control an external gas-driven extra-aortic balloon pump using an external microphone placed in the lumen of the extra aortic balloon or the gas line leading to the extra aortic balloon.

20. (Original): The method as claimed in claim 19, wherein the implanted gas line and balloon acts as a 'stethoscope,' and heart sounds can be detected intermittently or continuously, and sent directly to a controller positioned outside the patient's body.

21. (Original): The method as claimed in claim 20, wherein a percutaneous ECG lead is used to directly transmit the ECG signal to the controller.

22. (Original): The method as claimed in claim 21, wherein the ECG lead is combined with the percutaneous gas line.

23. (Original): The method as claimed in claim 21 wherein the ECG lead is separate from the percutaneous gas line.

24. (Currently Amended): The method as claimed in claim 22, further including a releasable and sealable connection for the percutaneous gas line and the ECG lead under the skin.

25. (Previously Presented): The method as claimed in claim 5, wherein the DSPT is able to receive signals from an external device to adjust digital signal processing variables within the DSPT for detecting and heart sounds.

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26. (Previously Presented): The method as claimed in claim 5, wherein the DSPT has a battery of sufficient life that the DSPT can be removed and replaced, independent of the cardiac sensing leads.

27. (Previously Presented): The method as claimed in claim 5, wherein the DSPT has a rechargeable battery that can be recharged by induction, or Transcutaneous Energy Transfer (TET).

28. (Previously Presented): The method as claimed in claim 5, wherein the DSPT can communicate directly with an implanted controller.

29. (Original): The method as claimed in claim 28, wherein the controller and the ECG and microphone are contained within the pump and the pump is positioned in the medial right chest, with one aspect of the pump (containing hermetically sealed microphone and ECG electrodes) against the right heart structures.

30. (Original): A dual channel DSPT configured for use in controlling the operation of a pulsatile heart assist device, the DSPT being of the type having an ECG channel and a phonocardiographic (PCG) channel, the DSPT being at least adapted to normally sense an electrical signal indicative of cardiac rhythm through the ECG channel, and to normally sense heart sounds through the PCG channel, and to transmit signals to an external receiver to control the timing of the pulsation of the heart assist device.

31. (Original): The DSPT as claimed in claim 30, wherein, signals are directly sent to an implanted controller.

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32. (Previously Presented): The DSPT as claimed in claim 30, wherein the DSPT is adapted to normally sense heart sounds through the PCG channel in the range of 20-500 Hz.

33. (Previously Presented): The DSPT as claimed in claim 30, wherein the DSPT is able to receive as well as transmit.

34. (Previously Presented): The DSPT as claimed in claim 30, wherein the DSPT has parameter settings adjustable within ranges, for detecting the R-wave and the Heart Sounds, and for the output signals.

35. (Previously Presented): The DSPT as claimed in claim 30, wherein the DSPT has other channels for detecting aortic and left ventricular blood pressure and for movement of the aortic or ventricular walls, and signals from these channels can also be interpreted to control heart assist device functioning.

36. (Currently Amended): In an apparatus~~Means~~ for controlling a co-pulsation or counter-pulsation heart assist device, the apparatus~~means~~ including: a co-or counter-pulsation heart assist device comprising a balloon, the improvement comprising; a controller for the heart assist device; and a DSPT of the type at least adapted to normally sense an electrical signal indicative of cardiac rhythm through an ECG channel and a sound signal indicative of heart sounds S1-I and/or S2 through a PCG channel, and to issue identifiable signals to the controller, in which the DSPT is set to issue pacing signals from the ventricular circuit at a minimum rate which is below a sensible rate in the event that the atrial circuit is unable to sense a rhythm signal from the patient's ventricle, and the controller is set to turn off the heart assist device in the event

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that the pacing signals that the controller receives from the DSPT are at a rate below a predetermined rate which is above the minimum rate.

37. (New) In a method of controlling an extra-aortic, counter-pulsation pulsatile heart assist device wherein said assist device comprises a balloon, the improvement comprising:

electrically detecting the R-wave of the heart's rhythm;

producing a signal to initiate a change in the pulsatile status of the assist device;

detecting a sound created by the closure of the aortic valve of the heart; and

producing a signal to return the heart assist device to the pulsatile status it had before detection of the R-wave.

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38. (New) In an apparatus for controlling a counter-pulsation heart assist device, the improvement comprising:

a pulsatile balloon pump adapted to be coupled to an aorta to compress it;

a controller for said pump;

a detector for electrically detecting the R-wave of a heart;

a first transmitter for sending a signal to said controller;

a second detector adapted to detect closure of an aortic valve;

a first transmitter for sending a signal to said controller;

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wherein said controller is adapted to respond to said signal from the first transmitter to change the pulsatile status of the heart assist device; and

wherein said controller is adapted to respond to said signal from said second transmitter to return the pulsatile status of the heart assist device which it had before receiving the signal from the first transmitter.